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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,215	02/08/1999	BILL H. MCANALLEY	013258.0172	9780

27683 7590 04/21/2004

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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/242,215	MCANALLEY ET AL.	
	Examiner	Art Unit	
	Michele C. Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 10, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-17,22-36,40-43 and 48-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-17,22-36,40-43 and 48-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/2000*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Prosecution Application

The request filed on March 10, 2004 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/242,245 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-17, 22, 27-36, 40-43, 48-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide prior support or antecedent basis for the language "the leaves and stems" in claims 1, 6, 22 and 40.

The claims as set forth in the amendment filed March 10, 2004, now recite a dietary supplement composition comprising a nutritionally effective amount of "isolated and purified saccharides". However, the specification as originally filed provides only for compositions comprising a nutritionally effective amount of a saccharide "in monomeric, oligomeric or polymeric and derivatized or underivatized form", as set forth on page 7, lines 23-27 of the present application.

Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure nor are there

specific examples of the newly limited genus which would show possession of the concept of a dietary supplement composition comprising a nutritionally effective amount of "isolated and purified saccharides". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above-mentioned claim limitations is considered to be the insertion of new matter for the above reasons.

As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Although not rising to the level of uncertainty, with regard to Claim 22, an apparent typographical appears in line 6. After "composition", Applicant should add the word and to place the claim in proper grammatical form.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (N).

Applicant claims a dietary supplement composition comprising: a nutritionally effective amount of at least six isolated and purified saccharides, wherein at least one of said six isolated and purified saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose, xylose and acetylated mannose; and wherein at least one of said six isolated and purified saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid and arabinogalactan. Applicant further claims a dietary composition according to claim 1, wherein at least one of said six isolated and purified saccharides is predigested from an oligomeic or polymeric form of saccharides as found in at least one of : a recited Markush group.

Yamada teaches a dietary supplement comprising a polysaccharide containing arabinose, galactose, glucose, rhamnose, galacturonic acid and glucuronic acid as the constituent saccharides. Yamada teaches that the dietary supplement comprising the polysaccharide improves hematopoietic function and serves as a radioprotective agent for treating or reducing the risk of radiation injury.

The reference anticipates the claimed subject matter.

Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated JP Endo (O).

Applicant's claimed invention of Claim 1 was set forth above. Applicant further claims a dietary supplement according to claim 1, further comprising a nutritionally effective amount of dioscorea complex.

Endo teaches a dietary composition which has a blood sugar lowering effect, wherein the oligo- or polysaccharides of the composition are digestible. The composition taught by Endo contains cellulose, methylcellulose, ethylcellulose, nitrocellulose, hydroxyethylstarch, carboxymethylstarch, mannan, pectin, pectic acid, aloe mucilage, chondroitin sulphuric acid, hyaluronic acid, heparin, laminarin, alginic acid, propylene glycol alginic acid ester, agar-agar, gum arabic, arabinogalactan, carrageenan, dammar gum, elemi gum, ghatti gum, guar gum, karaya gum, kauri gum, tragacanth gum, plantain seed gum, inulin, xylan, galactomannan, tamarind seed mucilage, quince seed mucilage, flax seed mucilage, okra mucilage, and *Dioscorea japonica* mucilage. Although the reference does not expressly teach that the composition comprises at least six of the claimed saccharides selected from the second group of claimed saccharides, the existence of N-acetylglucosamine from chitin, the existence of arabinose, galactose, glucuronic acid, the existence of mannosyluronic acid and gulosyluronic acid from alginic acid, the existence of arabinose, galactose, mannose, xylose and glucoronic acid from gum ghatti, the existence of galacturonic acid and sialic acid (N-acetylneuraminic acid), *etc.,* are inherent to the composition taught by Endo, as evidenced by the admitted prior art disclosed on page 11 in Table 3 of the instant application.

The reference anticipates the claimed subject matter.

Claims 1, 6, 16 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Kovacs (A).

Applicant's claimed invention of Claims 1 and 6 was set forth above. Applicant further claims a dietary supplement composition according to claim 1, further comprising a nutritionally effective amount of one or more non-toxic vitamins and minerals. Applicant further claims a dietary supplement composition according to claim 1 comprising a nutritionally effective amount of each of a least six isolated and purified saccharides, wherein at least a first one of said six isolated and purified saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose and xylose and said first of said six isolated and purified saccharides comprises from about 0.1 to about 75 weight percent of said composition; and wherein at least one of said six isolated and purified saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, and iduronic acid and said second one of said six isolated and purified saccharides comprises from about 0.1 to about 75 weight percent of said composition.

Kovacs teaches a dietary supplement comprising dehydrated mung bean sprout and beta-glucan enriched oat groat. In Column 5, lines 26-32, Kovacs teaches that the referenced dietary supplement comprises glucose (59.4%), xylose (20.2%), arabinose (12.4%), galactose (1.8%), mannose, rhamnose (1.8%), uronic acids (4.2%), minerals and vitamins. *See* also Column 7, lines 10-16.

The reference anticipates the claimed subject matter.

Claims 1, 6, 22, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke et al. (B).

Applicant's claimed invention of Claims 1, 6 and 22 was set forth above. Applicant further claims a dietary supplement composition according to claim 1, further comprising an herbal extract or plant extract of broccoli, brussel sprouts, cabbage, carrot, cauliflower, garlic, kale, onion, papaya, pineapple, tomato, asparagus, mushroom, parsnip, radish and turnip.

In Column 4, lines 11-40, Clarke teaches a pear (*Pyrus*) gum composition comprising rhamnose (2% w/w), fucose (3% w/w), arabinose (16% w/w), xylose (11% w/w), mannose (4% w/w), galactose (18% w/w), and glucose (46% w/w). In Column 11, lines 13-28, Clarke further teaches adding the referenced composition to garlic, mustard, parsley flakes, *etc.,* in the making of a salad dressing. It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-17 and 27-36 are rejected under 35 U.S.C. 103(a) as being obvious over Yamada et al. (N) in view of Cayen et al. (D), Endo (O), Hilsted (P), Graves (F), Balch et al. (U), Policappelli et al. (I), Shlyankevich et al. (J), Bonte et al. (K), Morrison (G), Dohnalek et al. (H), and McAnalley et al. (AD, U.S. Patent 5,308,838).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant's claimed invention of Claim 1 was set forth above. Applicant further claims a dietary supplement according to claim 1, further comprising a nutritionally effective amount of dioscorea complex. Applicant further claims a dietary supplement according to claim 1, further comprising a nutritionally effective amount of a blend of freeze-dried and powdered raw fruits and vegetables. Applicant further claims a dietary supplement according to claim 8, further comprising a nutritionally effective amount of a

xanthine and an herbal body-toning agent. Applicant further claims a dietary supplement according to claim 8, wherein said blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables comprises: broccoli, brussel sprouts, cabbage, carrot, cauliflower, garlic, kale, onion, papaya, pineapple, tomato and turnip. Applicant further claims a dietary supplement according to claim 7, further comprising a nutritionally effective amount of a beta sitosterol. Applicant further claims a dietary supplement according to claim 1, further comprising a nutritionally effective amount of a melatonin. Applicant further claims a dietary supplement according to claim 1, further comprising a nutritionally effective amount of a saccharide bioabsorption aid. Applicant further claims a dietary supplement according to claim 13, wherein the bioabsorption aid comprises soy lecithin. Applicant further claims a dietary supplement according to claim 1, further comprising a nutritionally effective amount of a dioscorea complex and a blend of freeze-dried and powdered raw fruits and vegetables. Applicant further claims a dietary supplement according to claim 8, further comprising a nutritionally effective amount of one or more non-toxic vitamins and minerals. Applicant further claims a dietary supplement according to claim 16, wherein: said vitamins comprise A, B1, B12, B2, B6, beta carotene, bioflavonoids, biotin, C, choline, D, E, folic acid, inositol, K, nicinamide, para-aminobenozoic acid, and panthothenic acid; and said minerals comprise boron, calcium, copper, GTF chromium, iodine, iron, magnesium, manganese, molybdenum, potassium, selenium, silicon, vanadium, and zinc. Applicant further claims a dietary supplement according to claim 1, wherein said blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables comprises: broccoli, brussel sprouts, cabbage, carrot, cauliflower, garlic, kale, onion, papaya, pineapple,

tomato and turnip. Applicant further claims a dietary composition according to claim 7, claim 28 and claim 29, wherein said composition comprises claim-designated weight percents of said saccharides and claim-designated weight percents of said dioscorea complex. Applicant further claims a dietary composition according to claim 8, claim 31 and claim 32, wherein said composition comprises claim-designated weight percents of said saccharides and claim-designated weight percents of said blend of freeze-dried and powdered raw fruits and vegetables. Applicant further claims a dietary composition according to claim 34 and claim 35, wherein said composition comprises claim-designated weight percents of said saccharides and claim-designated weight percents of said herbal or plant extract.

The teachings of Yamada were set forth above. Yamada teaches the claimed composition except for the instantly claimed ingredients. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the composition taught by Yamada to provide the claimed invention because at the time the invention was made Cayen, Endo, Hilsted, Graves, Balch, Dohnalek, Policappelli, Shlyankevich, Bonte, Morrison, and McAnalley teach the claimed ingredients as health-promoting agents. Firstly, Cayen teaches a composition comprising diosgenin (dioscorea complex) that is useful for lowering blood cholesterol and/or triglycerides, and which can be mixed with a beverage, for example water, milk or a fruit juice, or a food, for example, soups or a pulpy fruit. Like, Cayen, Endo also teaches a composition comprising dioscorea complex. For example, Endo teaches a dietary supplement comprising that has a blood sugar lowering effect, wherein the oligo- or polysaccharides of the composition are digestible. The composition taught by Endo contains cellulose,

methycellulose, ethycellulose, nitrocellulose, hydroethylstarch, carboxymethylstarch, mannan, pectin, aloe mucilage, chondroitin sulphuric acid, hyaluronic acid, heparin, laminarin, alginic acid, propylene glycol alginic acid ester, agar-agar, gum arabic, arabinogalactan, carrageenan, dammar gum, elemi gum, ghatti gum, guar gum, karaya gum, kauri gum, tragacanth gum, plantain seed gum, inulin, xylan, galactomannan, tamarind seed mucilage, quince seed mucilage, flax seed mucilage, okra mucilage, and *Dioscorea japonica* mucilage. Secondly, Hilsted teaches a composition comprising xanthines that are useful for counteracting hypoglycemia in diabetic patients. Thirdly, Graves teaches a modified, edible pulp as a dietary supplement having hypochloesteric effect, which is made from dietary fiber. Sources of dietary fiber are selected from raw fruits such as apples, oranges, and grapefruit; and, raw vegetables such as carrots, corn, peas, and sugar beets; and grasses such as sugar cane; and grains such as barley and rice (see Column 6, lines 49-55). The modified pulp may be milled to form a flour or granulated for use as a table-top dietary supplement that is sprinkled onto various foods. The granulated table-top product may be combined with various herbs and spices. In Column 6, lines 53, Graves teaches that the major constituents of typical dietary fiber include cellulose, hemicellulose, lignin, and pectin. Graves further teaches that pectin comprises the saccharides galactose, arabinose, xylose, and fucose. Fourthly, Balch teaches that melatonin, vitamins, and minerals are essential to life and the maintenance of health. In particular, Balch teaches melatonin, selenium, vitamin A, vitamin C, vitamin E, beta-carotene, and zinc as antioxidants which protect the body from the formation of free radicals that can cause damage to cell, impairing the immune system, and leading to infections and various degenerative diseases. Moreover, Balch

describes the disclosed vitamins and minerals as phytochemicals, which are biologically active substances found in fruits, vegetables, grains and legumes that appear to reduce the risk of cancer, heart disease, diabetes and high blood pressure. Balch specifically points to broccoli, brussel sprouts, cauliflower, cabbage, tomatoes and soybeans, as sources of plant materials containing health-benefiting phytochemicals, minerals, vitamins, and other nutrients. Furthermore, Dohnalek teaches a method of administering a therapeutic effective amount of powdered oligosaccharides, e.g., fructooligosaccharides (FOS), fructosans, xylooligosaccharides and galactooligosaccharides to humans for the reduction of diarrhea. In Column 2, lines 13-18, Dohnalek teaches that FOS occur in many plants, e.g., onions, garlic, asparagus, and tomatoes. Fifthly, Policappelli teaches herbal toning agents. For instance, Policappelli teaches a composition for dietary supplementation comprising herbal extracts combined with glucomannan or galactomannan, which is used for weight loss, weight control, and reduction of fats in the bodily organs. Both Shlyankevich and Bonte teach comprises beta-sitosterol which have beneficial health promoting effects. For instance, Shlyankevich teaches a composition for treating diabetic male sexual dysfunction comprising by weight in an inert carrier) 45-60 pts. phyto-oestrogen (calculated as isoflavone aglycone), 0-400 pts. phosphatidyl choline, 10-50 pts. beta-sitosterol, 30-100 pts. Damiana leaf dry extract, 0.15 pts. vitamin A, 0.-250 pts. vitamin B1, 0-300 pts. vitamin B6, 0-100 pts. vitamin E, 0-300 pts. Ca, 0-750 pts. Mg and 0-100 parts Zn, where the Ca, Mg and Zn are present as biologically-acceptable ingredients. Next, Bonte teaches a cosmetic or pharmaceutical composition comprising oxyacanthine and a saponin for stimulating hair growth or retarding hair loss, or

combating pruritus. The oxyancanthine, an antitumor drug, is extracted from a plant. In Column 3, lines 50-52, Bonte teaches that the saponin can be extracted from *Dioscorea*. Other ingredients further comprising the composition taught by Bonte include the trace elements zinc and selenium (Column 5, line 34), soya lecithin (Column 6, line 47), and beta-sitosterol (Column 6, line 54). Finally, Morrison teaches a food supplement comprising a combination of ingredients including soya lecithin and mucopolysaccharides, etc. (see abstract and Column 3, lines 10-29). In Column 1, lines 51 to Column 2, lines 1-11, Morrison teaches that the combination of the ingredients in his dietary supplement have a proven synergy shown by improved health against coronary artery disease, cerebrovascular disease, and intermittent claudication. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the ingredients taught by Cayen, Endo, Hilsted, Graves, Balch, Dohnalek, Policappelli, Shlyankevich, Bonte and Morrison to the dietary supplement composition taught by Yamada to provide the claimed composition because Cayen teaches and Endo teach their dietary supplements have a blood sugar lowering effect; Hilsted teaches that the xanthine composition of his invention are effective in improving the awareness of diabetic patients in the warning symptoms of hypoglycemic episodes and thus avoiding the distressful conditions thereof; and, thus are useful for counteracting hypoglycemia; Graves teaches his dietary supplement has enhanced hypocholesterolemic effect; Balch teaches the protective effects of the instantly claimed ingredients are found in plant materials and the claimed ingredients are often used in the making of multivitamin formulations, which can be sold as single dietary supplements; Dohnalek teaches that

his oligosaccharides or fructooligosaccharides can be incorporated into the making of tablets, follow-on formula, toddler's beverages, yogurts, milks, fruit juice, and dietary supplements (see Column 3, lines 47-63); Policappelli teaches that his compositions reduce hunger, burn fat, and activate the body's metabolism without obligation to physical exercise (see Column 3, lines 50 to Column 4, lines 1-6); Shlyankevich teaches that the beta-sitosterol containing composition is useful in the treatment of diabetic male sexual dysfunction; Bonte teaches that his novel formulation comprising for the combining of active substances enhances its therapeutic effects in the treatment of hair conditions; and Morrison teaches that lecithin has blood cholesterol lowering effect in patients with confirmed coronary heart disease (see Column 1, lines 48-50).

With regard to the instantly claimed ingredient of an herbal body-toning agent, the Office notes that although Graves mentions that his dietary supplement can further comprise various herbs, Graves does not expressly teach which herb can further comprise the referenced composition. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further add to the composition taught by Graves an herbal body-toning agent in the making of the instantly claimed dietary supplement because McAnalley teaches a composition comprising acemannan derived from aloe. McAnalley teaches that the composition is effective in treating a number of disease conditions where the principal mechanism of resolution or cure system requires intervention by the patient's immune system. One of ordinary skill in the art at the time the invention was made would have been motivated and one would have had a reasonable expectation of success to modify the composition taught by Graves to make the claimed dietary supplement because McAnalley teaches that the

composition is effective for treating cancer, viral diseases, respiratory and immune respiratory diseases, inflammations, infections, infestations by administering an effective amount of acetylated mannan derivative, such as acemannan derived from aloe.

This rejection is based on the well established proposition of patent law that no patentable invention resides in combining old ingredients of known characteristics where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518: In re Huellmantel 139 USPQ 496; In re Crockett et al., 1266 USPQ 186.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 40, 48-52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. (AQ or V, Robert K. Murray et al., Harper's Biochemistry, Appleton & Lange, 1996, pages 648-649.).

Applicant claims a dietary supplement composition comprising: a nutritionally effective amount of isolated and purified galactose, glucose, mannose, N-

acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose. Applicant claims a dietary supplement composition according to claim 41, wherein said galactose, glucose, mannose, N-acetylgalactosamine, N-acetylglucosamine, xylose and rice flour are present in said composition in a weight ratio of about 1:1:1:1:1:1:1:1:8. Applicant claims a dietary supplement composition according to claim 40, wherein said isolated and purified saccharides are powdered, are encapsulated, are in solution, wherein said claim-designated isolated composition comprises from about 1 to about 48 weight percent of each said isolated and purified claim-designated saccharides, and wherein said claim-designated isolated composition comprises from about 1 to about 10 weight percent of each said isolated and purified claim-designated saccharides. Applicant further claims a dietary supplement composition according to claim 41, wherein said isolated and purified claim-designated saccharides are isolated and purified from a recited predigested Markush group.

On page 650, in Table 56-4, Murray teaches that galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose are the principal sugars found in human glycoproteins.

The teachings of Murray are set forth above. Murray does not teach a composition comprising the instantly claimed saccharides. However, it would have been obvious to one of ordinary skill in the art to combine the sugars taught by Murray to provide the instantly claimed dietary supplement because at the time the invention was made it was known in the art of that the instantly claimed sugars were principal the building blocks of glycoproteins found in humans and important in the phenomenon of metastasis, especially metastasis in cancer cells. At the time the invention was made,

one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to combine the instantly claimed saccharides in the making of the claimed composition because Murray teaches that galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose are the principal sugars found in human glycoproteins, which have numerous and diverse biological functions, as set forth in Table 56-2. Furthermore, on page 665 to page 666, under "*SUMMARY*" Murray teaches, "The oligosaccharide chains are important to glycoproteins in modulating their solubility and viscosity, in protecting them against proteolysis, in their biologic actions, and in their participation in normal and abnormal cell-cell interactions (eg, sperm-egg interaction, development, and cancer, respectively.). Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention may be predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

With regard to the claim limitations of Claims 48-50 wherein Applicant directs the invention to a dietary supplement wherein the dietary supplement is either powdered, encapsulated or in a solution, at the time the invention was made, it also would have been obvious to one ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation of success to combine the instantly claimed saccharides taught by Murray in any of the instantly claimed forms because the claim-designated forms are no more than conventional pharmaceutical forms for the delivery of an active ingredient. Thus, at the time the invention was made the choice of either a powder, an encapsulated form or a solution comprising the instantly claimed saccharides would have been merely a matter of design choice to one practicing the invention given that the claimed forms are conventional forms to deliver a drug.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 40-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray et al. (AQ or V, Robert K. Murray et al., Harper's Biochemistry, Appleton & Lange, 1996, pages 648-649.) in view of Vanderveer et al. (L) and Tamai (Q). Applicant's claimed invention of Claims 40, 48-52 and 54 was set forth above. Applicant claims a dietary supplement composition according to claim 40, wherein said composition further comprises rice flour. Applicant claims a dietary supplement composition according to claim 41, wherein said composition comprises a flowing agent and a lubricant. Applicant further claims a dietary supplement according to claim 41, wherein said claim-designated saccharides are isolated and purified from a recited Markush group wherein the ingredients thereof are predigested.

The teachings of the dietary supplement composition comprising the instantly claim-designated saccharides taught by Murray are set forth above. The teachings of Murray teach the claimed composition except for rice flour, a flowing agent and a lubricant, and wherein the claim-designated saccharides are isolated and purified from a recited Markush group wherein the ingredients thereof are predigested. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the composition taught by the teachings of Murray as set forth immediately above because Vanderveer teaches a dietary supplement composition comprising rice flour that is useful in reducing the risk of colon cancer and Tamai teaches a dietary health-food composition comprising rice flour, yam, herbs, and gold or silver foils (flow agent) that is useful in reducing the risk of obesity. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add rice flour to the

composition taught by Murray that comprises each of the claim-designated saccharides to provide the instantly claime invention because both Vanderveer and Tamai teach dietary supplements comprising rice flour have beneficial health promoting effects.

With regard to the claim limitation of Claim 42 wherein Applicant claims a dietary supplement composition further comprising a flowing agent and a lubricant, it also would have been obvious to one ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation of success to combine the instantly claimed saccharides taught by Murray the instantly claimed ingredients of a flowing agent and a lubricant because the instantly claimed ingredients are conventional additives known in the art of pharmacy as being useful in the making of drugs. Thus, at the time the invention was made the addition of a flowing agent and a lubricant to the composition taught by Murray comprising the instantly claimed saccharides would have been merely a matter of design choice to one practicing the invention given that the claimed ingredients are conventional ingredients used in the making of pharmaceuticals to deliver a drug.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele C. Flood whose telephone number is (571) 272-0964. The examiner can normally be reached on 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Michele C. Flood

MICHELE FLOOD
PATENT EXAMINER

MCF
April 18, 2004